

LABEL IN PART: (Vial and case) "30 cc. * * * Li-Bex With Iron Each 2 cc. Represents Vit. B-12 Activity (From Liver Inj. U.S.P. Beef) Equivalent to: Cyanocobalamin 1.0 mcgm. * * * Caution:" and "10 cc. Vial Succinylcholine Chloride Injection 20 mg. per cc. * * * Warning: For use only by skilled anesthetists with facilities for immediate artificial respiration. Manufactured for Wittney & Co., Inc. Denver, Colorado."

ACCOMPANYING LABELING: Leaflet entitled "Succinylcholine Chloride Injection."

RESULTS OF INVESTIGATION: The leaflets were prepared by the dealer and the labels of *succinylcholine chloride injection* were supplied to the manufacturer by the dealer. The *Li-Bex with iron* was shipped by Medical Chemicals Corp., Chicago, Ill.

LIBELED: 2-21-62, Dist. Colo.

CHARGE: (*Li-Bex with iron*) 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to the drug; (*succinylcholine chloride injection*) and 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was a drug intended for veterinary use which, because of its toxicity or other potentiality for harmful effect, or the method for its use, was not safe for animal use except under the supervision of a licensed veterinarian, and its label failed to bear the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian," and its label also failed to bear the recommended or usual dosage for each animal species for which the article was intended.

DISPOSITION: 4-9-62. Consent—claimed by Lyle A. Wittney & Co., Inc. The *Li-Bex with iron* was destroyed and the *succinylcholine chloride injection* was released under bond for relabeling.

7004. Tain oral suspension and Tain Inlay-Tab tablets. (F.D.C. No. 46967. S. Nos. 27-395/6 T, 28-879/80 T, 29-401/2 T.)

QUANTITY: 131 8-oz. ctnd. btls. and 183 50-tablet ctnd. btls.; 9 cases, 12 50-tablet ctnd. btls. each, and 5 cases, 12 8-oz. ctnd. btls. each; and 14 8-oz. ctnd. btls. and 33 50-tablet ctnd. btls., at Kansas City, Mo.

SHIPPED. Between 12-29-61 and 1-29-62, from Lincoln, Nebr., by Dorsey Laboratories.

LABEL IN PART: (Btl. and ctn.) "8 Fl. Oz. List No. 6050 Dorsey Tain Oral Suspension Caution * * * Dorsey Laboratories a division of the Wander Company, Lincoln, Nebraska * * * Each Teaspoonful (5 ml.) contains: Triacetyloleandomycin 125 mg. Triaminic^R 25 mg. (phenylpropanolamine hydrochloride) 12.5 mg. pheniramine maleate 6.25 mg. pyrilamine maleate 6.25 mg. Acetaminophen 150 mg. * * * Expiration Date May '63"; (ctn. only) "Triacetyloleandomycin is effective against most gram positive organisms involved in respiratory infections. * * * Has analgesic and antipyretic action * * * is an effective oral nasal decongestant and has antihistaminic action"; and (50-tablet btl. and ctn.) "50 Tablets List No. 1339 Dorsey Tain Antibiotic Decongestant Analgesic Each Tain Inlay-Tab contains: Triacetyloleandomycin equivalent to 125 mg. oleandomycin Triaminic^R 25 mg. phenylpropanolamine hydrochloride 12.5 mg. pheniramine maleate 6.25 mg. pyrilamine maleate 6.25 mg. Calurin^R (calcium acetylsalicylate carbamide) (equivalent to aspirin 300 mg.) Caution: * * * Dorsey Laboratories a division of The Wander Company Lincoln, Nebraska Expiration Date Dec. '63."

ACCOMPANYING LABELING: Leaflet entitled "Dorsey Tain[®] Composition" and folder entitled "Time to Take 'Em Out Again."

RESULTS OF INVESTIGATION: New drug applications for these articles were made effective with labeling offering them specifically for the "symptomatic relief of the common cold (malaise, headache, muscular cramps, aches and pains) and the prevention of secondary complications due to susceptible organisms" and with the caution that "if resistant infection or super infection appears discontinue the drug and institute specific therapy or supportive treatment," whereas the article was being recommended and suggested for the treatment of susceptible infections which complicate the common cold, other respiratory infections and other infections.

LIBELED: On or about 2-13-62, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective as a treatment for tonsillitis, pharyngitis, otitis media, bronchitis, pneumonitis, bronchopneumonia, rhinitis, cervical lymphadenitis, coryza, lobar pneumonia, tracheitis or tracheobronchitis, influenza, adenoiditis, bronchial asthma, croup and postnasal infection; that the analgesic ingredient, namely, acetaminophen, was safer in children than salicylates; that the antipyretic effect of the articles did not mask the diagnostic importance of persistent fever; and (*Tain oral suspension*) that it met pediatric requirements in upper respiratory infections; that when side effects occur they were not usually attributable to the article; that the article was an upper respiratory infections antibiotic proved effective in pediatric use; that it was indicated in the treatment of susceptible infections which complicate the common cold, and other respiratory infections; that children did not become drowsy from antihistamines; 502(f) (1)—the labeling failed to bear adequate directions for use and the articles were not exempt from the requirement, since the promotional material for the articles was not the same as, or substantially the same as, the labeling authorized by the new drug applications filed with respect to the articles; and 505(a)—the articles were new drugs, and the new drug applications filed with respect to the articles did not apply to the conditions for which the articles were promoted to the medical profession as set forth in statements contained in the promotional material.

DISPOSITION: 4-24-62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

7005. Streptomycin-procaine penicillin. (F.D.C. No. 47744. S. No. 32-899 T.)

QUANTITY: 448 vials at Los Angeles, Calif.

SHIPPED: During 1960, from New York, N.Y.

LABEL IN PART: "Control: 7G50 10 cc. Streptomycin-Procaine Penicillin Aqueous Suspension Procaine Penicillin 400,000 Units Streptomycin 0.5 Gm. Base per 2 cc."

RESULTS OF INVESTIGATION: Assay showed no significant penicillin potency in the article.

LIBELED: 6-11-62, S. Dist. Calif.